Claims

1. Biopsy device for tissue collection in the form of a handpiece with at least one spring-loadable clamping and launch device in the form of a clamping carriage (28) for a biopsy needle unit, comprising an outer hollow needle (3) with a scarfed cutting blade on the distal side and a hollow biopsy needle (2) on bearings inside the outer hollow needle (3), with a tissue sample collection area (71) provided in its distal end area, whereby the outer hollow needle (3) relative to the hollow biopsy needle (2) is on sliding bearings, and with a pressure source (5), which is combinable with the hollow biopsy needle (2), characterized in that the handpiece comprises an enclosure, inside of which the following components are permanently integrated:

- at least a first and second drive unit (21, 58),
- the clamping carriage (28), which can be linked with the first drive unit (21) in such a fashion that the clamping carriage (28) can be placed in a clamped state and is lockable in this state,

that the enclosure comprises at least one enclosure cover (10), and
that the following components are detachably permanently integratable in the inside of the enclosure in an open position of the enclosure cover (10),

- the biopsy needle unit, which is on bearings in a biopsy needle holder (37), which can be linked at least with the clamping carriage (28), whereby the distal needle areas of the outer hollow needle (3) and the hollow biopsy needle (2) for tissue collection extend outside the enclosure, and
- the pressure source (5), which in the proximal area of the hollow biopsy needle (2) is connected gastight with same via at least one connecting conduit (4) and which can be linked with the second drive unit (58) to produce a pressure level, whereby the connecting conduit (4) runs at least partially inside the enclosure.

2. Biopsy device according to Claim 1,
characterized in that the biopsy needle unit is detachably permanently integrated in the biopsy needle holder (37), whereby
the inner biopsy needle (2) is connected on the proximal side with a fitting (47), via which the connecting conduit (4) is combinable in a gastight fashion with the inner biopsy needle (2) and which contains a fixing profile (49), which can be used in a counter profile provided inside the biopsy needle holder (37) in such a fashion that the inner biopsy needle (2) at least in lengthwise direction of the needle fits snuggly in the biopsy needle holder, and

the outer hollow needle (3) is provided with a thread profile (73) in at least one subsection along its circumference, which meshes in such a fashion at least detachably permanently with the biopsy needle holder (37) connected to the counter thread profile (75) that the outer hollow needle (3) is movable in a lengthwise direction of the needle relative to the inner biopsy needle (2).

3. Biopsy device according to Claim 2,
characterized in that a drive (74) is affixed to the circumference of the outer hollow needle (3), which can be linked with the first drive unit (21), which can produce rotation of the outer hollow needle (3) in the lengthwise direction of the needle, whereby the outer hollow needle (3) is axially movable relative to the biopsy needle holder (37) and thereby to the hollow biopsy needle (2).

4. Biopsy device according to Claim 2,
characterized in that the fitting (47) is provided with a latching component (50), which contacts the biopsy needle holder's (37) active areas in such a fashion that the inner biopsy needle (2) fits snuggly latchable in its lengthwise direction of the needle in preselected positions.

5. Biopsy device according to Claim 2,
characterized in that a means increasing the friction between both needles is provided between the outer hollow needle (3) and the hollow biopsy needle (2).

6. Biopsy device according to Claim 5,
characterized in that the fitting (47) is provided with a latching component (50), which contacts the active areas of the biopsy needle holder (37) in such a way that the inner biopsy needle (2) in its lengthwise direction of the needle in preselected positions is latchable in such a fashion that a clearance exists between the active areas and the latching component enabling an angle-limited rotation of the hollow biopsy needle (2) around its longitudinal axis in both directions of rotation.

7. Biopsy device according to Claim 3 and 6,
characterized in that by reciprocal rotation of the outer hollow needle (3), driven via the drive (74) meshing with the first drive unit (21), the hollow biopsy needle (2) due to the increased friction between the two needles (2, 3) also rotates, whereby the rotating motion of the hollow biopsy needle (2) is limited in both directions of rotation by the clearance-influenced latching component (50).

8. Biopsy device according to Claim 1,
characterized in that an elastic sealing component (76) is provided on the outer hollow needle (3) and the hollow biopsy needle (2), which seals gastight both of the needles (2, 3) from each other.

9. Biopsy device according to Claim 2,
characterized in that the biopsy needle holder (37) is provided with a clutch structure (77), which can be used in a counter clutch structure (40) provided on the clamping carriage (28).

10. Biopsy device according to Claim 1,
characterized in that the pressure source (5) is provided with a piston cylinder unit (69), which, depending on piston movement, can produce a prevailing pressure as lower pressure or overpressure inside the cylinder unit.

11. Biopsy device according to Claim 10,
characterized in that the cylinder unit (52) is designed in the form of a spray body and comprises a cylinder floor (51) with a connecting piece (63) for a gastight connection to the connecting conduit (4) and a cylinder port opposite the cylinder floor (51),
that the piston unit is provided with a threaded spindle (53), on one end of which the piston (54) is affixed, while the other end, a threaded spindle thread (48) provided on the cylinder port of the cylinder unit (52) protrudes, which comprises a gearwheel-like surface profile (55), which can be meshed with the second drive unit, and
that when the threaded spindle thread (48) is rotated, the threaded spindle (53) and piston (54) is axially movable relative to the cylinder unit (52).

12. Biopsy device according to Claim 10 or 11,
characterized in that the cylinder unit (52) in the area of the cylinder port inside the cylinder wall is provided with at least one vent hole (67), so that in a piston position near the cylinder port, the cylinder area enclosed between the piston (54) and the cylinder floor (51) is ventable.

13. Biopsy device according to Claim 10,
characterized in that the piston cylinder unit (69) comprises a cylinder longitudinal axis,
that the piston cylinder unit (69) is arranged in such a fashion next to the biopsy needle unit inside the enclosure that the needle longitudinal axis of the biopsy needle unit and the cylinder axis of the piston cylinder unit (69) run co-parallel, and
that the connecting conduit (4) comprises a U-shaped line path.

14. Biopsy device according to one of the Claims 1 through 13,

characterized in that the connecting conduit (4) is a flexible, optically largely transparent hose pipe, which permits relative motion between pressure source (5) and hollow biopsy needle (2).

15. Biopsy device according to one of the Claims 1 through 14,
characterized in that the biopsy needle unit integrated in a biopsy needle holder (37) and the pressure source (5) which is connected gastight with the hollow biopsy needle (2) via the connecting conduit (4) are designed as a uniform module (29) which can be used in the enclosure and then removed from the enclosure.

16. Biopsy device according to Claim 15,
characterized in that the module (29) consisting of a biopsy needle holder (37), in which the biopsy needle unit is integrated, connecting conduit (4) and pressure source (5) is detachably permanently usable in a spatially permanently provided arrangement in an insertion aid (109), by means of which the module (29) can be used inside the enclosure.

17. Biopsy device according to Claim 3,
characterized in that the clamping carriage (28) by means of the drive (74), which is connected to a drive shaft of the first drive unit (21), and the thread profile (73) which can be made to rotate and the thereby possible axial motion of the outer hollow needle (3) can be placed in the clamped state, whereby the drive (74) is supported on one side by a fixing device serving as a mechanical counter bearing (36), which is provided as fixed casing and that it is mechanically lockable when it reaches the clamped state of the clamping carriage (28).

18. Biopsy device according to Claim 1 and 17,
characterized in that in the clamped state the locked clamping carriage (28) can be released by a release mechanism, whereby the clamping carriage (28) and the biopsy needle holder (37) connected to it can be abruptly placed in the relaxed state, whereby the biopsy needle unit, i.e. the outer hollow needle (3) and the hollow biopsy needle (2), are jointly moved on the distal side.

19. Biopsy device according to Claim 3 or 17,
characterized in that the first drive unit (21) as drive shaft is provided with a toothed roller (23), which meshes with the drive designed as a gear wheel (74).

20. Biopsy device according to Claim 1,
characterized in that the first and second drive unit (21, 58) is designed as a DC electrical motor with a post-connected planetary gear train.

21. Biopsy device according to Claim 11 and 20,
characterized in that the second drive unit (58) is provided with a drive shaft having a drive pinion (56), which can be meshed with the gearwheel-like surface profile (55) of the threaded spindle thread (48) of the piston cylinder unit (69).

22. Biopsy device according to Claim 1,
characterized in that a base unit (8) is provided, which is permanently detachably connected with the inside of the enclosure, which in turn is provided with recesses to affix the first and second drive unit (21, 58) in such a fashion that its drive shaft are separated from each other and run parallel to one another,
that the base unit (8) is provided with a stop component (26), from which a guide pin (30) originates, along which the spring loading mechanism of the clamping carriage (28) is guided, and
that the base unit (8) is provided with recesses to insert the biopsy needle unit into the biopsy needle holder (37) and which allow positioning of the pressure source (5).

23. Biopsy device according to Claim 22,
characterized in that the clamping carriage (28) along the guide pin (30) is spring loadable on both sides, that in the relaxed state the clamping carriage (28) can be deflected from the rest position from both sides along the guide pin (30).

24. Biopsy device according to Claim 1,
characterized in that a energy supply unit (11) is provided inside the enclosure in the form of a non-rechargeable battery or a rechargeable battery.

25. Biopsy device according to Claim 24,
characterized in that the energy supply unit is separated (114) from the area of the clamping carriage (28) and the pressure source (5) by a separator.

26. Biopsy device according to Claim 1,
characterized in that a control unit is provided in the enclosure to drive the first and second drive unit (21, 58), and
that the control unit and releasing the latch of the clamping carriage (28) can be operated using a console (57) affixed to an outer wall of the enclosure.

27. Biopsy device according to Claim 26,
characterized in that the control unit to control the drive units designed as a DC electrical motor comprises a tachometer unit.

28. Biopsy device according to Claim 27,
characterized in that each tachometer unit is operated optically using a photocell and a sensor located directly against the drive shaft.

29. Biopsy device according to Claim 26,
characterized in that the control unit is provided with at least one programmable microprocessor.

30. Biopsy device according to Claim 26,
characterized in that the console comprises at least the following user touch panels (88, 89, 90), each of whose control options and functions can be indicated by optical signals (91, 92, 93, 94, 95):

- a "biopsy touch panel" (89) with three functions, whose different functions are each tagged by different optical signals (91, 92, 93), and comprises the following functions:
  - reset function (91), i.e. placing of all of the components integrated in the enclosure into a required position,
  - tissue collection function (92), i.e. building of low pressure inside the hollow biopsy needle by means of the pressure source, opening of the tissue sample collection area (71) by retracting the outer hollow needle (3) with respect to the hollow biopsy needle (2), cutting sequence by periodic axial back- and forth motions of the hollow biopsy needle (2) and tissue detachment sequence by feeding the outer hollow needle (3) beyond the tissue sample collection area (71) with respect to the hollow biopsy needle (2), ventilating the pressure source (5) to decrease low pressure,
  - Tissue ejection function (93), i.e. partial opening of the tissue sample collection area (71) by incomplete retraction of the outer hollow needle (3), increasing overpressure inside the pressure source, by which the separated tissue from the tissue sample collection area (71) is separated and complete retraction of the outer hollow needle (3) and thereby complete opening of the tissue sample collection area (71),
- "Clamping touch panel" (90), whose actuation of the clamping carriage (28) brings it into the clamped state and
- "Launch touch panel" (88), whose actuation of the clamping carriage (28) and the biopsy needle unit on the distal side launches a certain path distally.

31. Biopsy device according to Claim 23 and 30,
characterized in that during the cutting sequence, the control unit for performing the tissue collection function moves the first drive unit in a short periodic sequence in the respective opposite directions of rotation, such that the outer hollow needle (3) and the hollow biopsy needle (2) produce back and forth motions along its needle longitudinal axis.

32. Biopsy device according to Claim 30,
characterized in that the control unit is provided with a safety delay, in which the operation of at least the clamping touch panel (90) function and the tissue ejection function is time-delayed compared to the performance of the other control touch panels.

33. Biopsy device according to Claim 1,
characterized in that the enclosure has the form of a cuboid, with an enclosure cover (10) hinged on the enclosure and a first and second face (6, 7), whereby the first face (6) is provided with at least one opening, through which the distal needle areas of the outer hollow needle (3) and of the hollow biopsy needle (2) for tissue collection project outside the enclosure, and the second face (7) is provided with at least two recesses (15, 16), through which at least the connecting conduit (4) is guided.

34. Biopsy device according to Claim 33,
characterized in that a microswitch (19) is provided in the recess (16) of the second face (7), which can be operated when the enclosure is closed via the pressure source (5), whereby an energy supply can be released for the drive units (21, 58).

35. Biopsy needle module for implementation in a biopsy device according to one of the Claims 1 through 34, which comprises the following components:
- a biopsy needle unit integrated in a biopsy needle holder (37), which comprises an outer hollow needle (3) with a cutting blade scarfed on the distal side and a hollow biopsy needle (2) on bearings inside the outer hollow needle (3), with a tissue sample collection area (71) provided at its distal end area, whereby when turned the outer hollow needle slides relative to the inner hollow needle (2),
- a connecting conduit (4) and
- a pressure source (5), whereby the connecting conduit (4) the hollow biopsy needle (2) is connected gastight with the pressure source (5).

36. Biopsy needle module according to Claim 35,

characterized in that the biopsy needle unit is detachably permanently integrated in a biopsy needle holder (37), whereby the inner biopsy needle (2) is connected on the proximal side with a fitting (47), via which the connecting conduit (4) is combinable in a gastight way with the inner biopsy needle (2) and which comprises a fixing profile (49), which is usable in a counter profile provided inside the biopsy needle holder (37) in such a fashion that that the inner biopsy needle (2) is fixed in the biopsy needle holder at least in lengthwise direction of the needle, and
the outer hollow needle (3) is provided in at least a section along its circumference with a thread profile (73), which is meshed in such a fashion with a counter thread profile (75) at least detachably permanently connected with the biopsy needle holder (37) that the outer hollow needle (3) is movable relative to the inner biopsy needle (2) in the lengthwise direction of the needle.

37. Biopsy needle module according to Claim 35,
characterized in that a drive (74) is fixed to the circumference of the outer hollow needle (3), through which the outer hollow needle (3) can be placed in rotation in the lengthwise direction of the needle, whereby the outer hollow needle (3) is axially movable relative to the biopsy needle holder (37) and thereby to the hollow biopsy needle (2).

38. Biopsy needle module according to Claim 35,
characterized in that the fitting (47) is provided with a latching component (50), which contacts active areas des biopsy needle holder (37) in such a fashion that the inner biopsy needle (2) fits snuggly latchable in the lengthwise direction of the needle in providable positions.

39. Biopsy needle module according to Claim 35,
characterized in that between the outer hollow needle (3) and the hollow biopsy needle (2) a means enhancing the friction between the two needles is provided, which is designed in the form of a sealing component (76).

40. Biopsy needle module according to Claim 39,
characterized in that the fitting (47) is provided with a latching component (50), which contacts active areas of the biopsy needle holder (37) in such a fashion that the inner biopsy needle (2) is latchable around its lengthwise direction of the needle positions in such a fashion that a clearance exists between the active areas and the latching component permitting an angle-limited rotation of the hollow biopsy needle (2) around its longitudinal axis in both directions of rotation.

41. Biopsy needle module according to Claim 35,

characterized in that the biopsy needle holder (37) comprises a clutch structure (77), which can be used in a counter clutch structure (40) provided on a clamping carriage (28).

42. Biopsy needle module according to Claim 35,
characterized in that the pressure source (5) comprises a piston cylinder unit (69), which can produce a prevailing pressure level as low pressure or overpressure depending on the piston motion inside the cylinder unit.

43. Biopsy needle module according to Claim 42,
characterized in that the cylinder unit (52) is designed in the form of a spray body and comprises a cylinder floor (51) with a connecting piece (63) for a gastight connection to the connecting conduit (4) and a cylinder port opposite the cylinder floor (51),
that the piston unit is provided with a threaded spindle (53), on one end of which the piston (54) is affixed, while on the other end, a threaded spindle thread (48) provided on the cylinder port of the cylinder unit (52) protrudes, which comprises a gearwheel-like surface profile (55), which can be meshed with a drive unit, and
that when the threaded spindle thread (48) is rotated, the threaded spindle (53) and piston (54) is axially movable relative to the cylinder unit (52).

44. Biopsy needle module according to Claim 43,
characterized in that the cylinder unit (52) in the area of the cylinder port inside the cylinder wall is provided with at least one vent hole (67), so that in a piston position near the cylinder port the cylinder area enclosed between the piston (54) and the cylinder floor (51) is ventable.

45. Biopsy needle module according to Claim 42,
characterized in that the piston cylinder unit (69) comprises a cylinder longitudinal axis,
such that the piston cylinder unit (69) is arranged in such a fashion alongside the biopsy needle unit that the needle longitudinal axis of the biopsy needle unit and the cylinder longitudinal axis run co-parallel, and
that the connecting conduit (4) has a U-shaped line path.

46. Biopsy needle module according to Claim 35,
characterized in that the connecting conduit (4) is a flexible, largely optically transparent hose pipe, which permits relative motion between the pressure source (5) and hollow biopsy needle (2).

47. Biopsy needle module according to Claim 35,

characterized in that the biopsy needle module consisting of biopsy needle holders (37), in which the biopsy needle unit is integrated, connecting conduit (4) and pressure source (5) is detachably permanently usable in a spatially permanently provided arrangement in an insertion aid (109).

48. Biopsy needle module according to Claim 35 or 36,
characterized in that the tissue sample collection area (71) is axially limited by two longitudinal edges, which are designed as cutting edges (68).

49. Biopsy needle module according to Claim 48,
characterized in that the hollow biopsy needle (2) at least in the area of the tissue sample collection area (71) is designed in the form of a straight hollow cylinder, which is provided with a local axial recess, whose radial depth is less than half the interior diameter of the hollow cylinder, and whose longitudinal edges limiting recess axially on both sides are designed as cutting edges in such a fashion that in the area of the longitudinal edges the inner radius describing the hollow cylinder continuously fits the outer radius.

50. Biopsy needle module according to Claim 35,
characterized in that the hollow biopsy needle (2) on the proximal end of the tissue sample collection area (71) is provided with a constriction which narrows the cross-section of the hollow channel enclosed by the biopsy needle, which leaves open a hollow channel permeation opening in the tissue sample collection area (71) in the lower area of the tissue sample collection area (71).

51. Biopsy needle module according to Claim 50,
characterized in that the constriction covers ca. 60 - 70% of the hollow channel cross-section, and the constriction is designed in the form of a plug protruding into the hollow channel or as a surface element protruding into the cross-section area of the hollow channel.

52. Biopsy needle module according to Claim 36,
characterized in that on the distal side of the biopsy needle holder (37) a guide roller (81) is provided in a sliding fashion resting against the circumference of the outer hollow needle (3), which comprises a largely perfectly fitting sized permeation opening on the circumference of the outer hollow needle (3), through which the outer hollow needle (3) passes, and can be used in a bushing (13) in the distal enclosure cover (6).

53. Process for tissue collection using a biopsy device with at least one spring-loadable clamping carriage (28) for a biopsy needle unit which comprises a outer hollow needle (3) with a

scarfed cutting blade on the distal side and a hollow biopsy needle (2) on bearings inside the outer hollow needle (3), with a tissue sample collection area (71) provided in its distal end area, whereby the outer hollow needle (3) relative to the hollow biopsy needle (2) is on sliding bearings, and with a pressure source (5), which is combinable with the hollow biopsy needle (2), characterized by the combination of the following sequential steps:

- Placement of the clamping carriage and the biopsy needle unit into a initial position required for tissue collection,
- Injection of the biopsy needle unit into a tissue area to be examined, whereby the outer hollow needle (2) while the injection sequence closes the tissue sample collection area (71) of the hollow biopsy needle (2),
- creation of low pressure inside the hollow biopsy needle,
- opening of the tissue sample collection area (71) by withdrawing the outer hollow needle proximally to the tissue sample collection area (71), whereby due to the prevailing low pressure within the tissue sample collection area (71), surrounding tissue is sucked into the tissue sample collection area (71),
- Axially reciprocal distal and proximal motion of the hollow biopsy needle (2), whereby the tissue is severed by the cutting effect of the longitudinal edges formed as cutting edges on the lateral limits of the tissue sample collection area (71),
- Severing of a tissue sample inserted into the tissue sample collection area (71) tissue sample by feeding the outer hollow needle (3) in a distal side twisting motion beyond the tissue sample collection area (71) by means of the scarfed cutting blade,
- ventilation of the interior of the hollow biopsy needle (2),
- removal of the biopsy needle unit from the tissue area to be studied and
- tissue collection from the tissue sample collection area (71) by opening the tissue sample collection area (71) by means of proximal side shifting of the outer hollow needle (3) to a position in which the hollow needle still covers a proximal area of the tissue sample collection area (71) and creation of overpressure along the hollow biopsy needle (2), which spreads into the tissue sample collection area (71), as a result of which the tissue sample detaches from the floor of the tissue sample collection area (71) for collection.

54. Process according to Claim 53,
characterized in that the axially reciprocal distal and proximal motion of the hollow biopsy needle (2) to produce an increased tissue separation effect is superimposed on a reciprocal rotational motion around the longitudinal axis of the hollow biopsy needle.

55. Process according to Claim 53,

characterized in that the placement of the clamping carriage (28) and the biopsy needle unit in an initial position required for tissue collection is automatically initiated by closing the enclosure cover (10), whereby an electronic control system which controls the drive units (21, 58) is activated in such a fashion that the biopsy needle unit and the clamping carriage (28) contained in the biopsy needle holder (37) are placed in a initial position.

56. Process according to Claim 55,
characterized in that the electronic control system recognizes by a tactile and/or optical sensor (130) whether the biopsy needle holder (37) is inserted into the enclosure.